



I029460

November 30, 2016

Documents Processing Desk – 6(a)(2)  
U.S. Environmental Protection Agency  
Office of Pesticides Programs  
One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202

RE: FIFRA Section 6(a)(2) Report  
Ceva Animal Health, LLC – Company Number 83399

Dear Sir/Madam:

In accordance with FIFRA § 6(a)(2), Ceva Animal Health, LLC is submitting the 3<sup>rd</sup> Quarter (Jul-Sep) 2016 aggregate reports for the following product registrations:

- EPA Reg. No. 83399-6 sold under the brand names Vectra 3D For Dogs and SimpleGuard3 For Dogs; also sub-registered as First Shield Trio For Dogs, EPA Reg. No. 83399-6-85581
- EPA Reg. No. 83399-9 sold under the brand names Vectra for Cats, Vectra for Cats and Kittens, & SimpleGuard for Cats and Kittens; also sub-registered as First Shield for Cats, EPA Reg. No. 83399-9-85581
- EPA Reg. No. 83399-10 sold under the brand name Vectra for Dogs and Puppies; also sub-registered as First Shield Dog and Puppy, EPA Reg. No. 83399-10-85581
- EPA Reg. No. 83399-12 sold under the brand name Vectra Pro Flea Spray
- EPA Reg. No. 83399-16 sold under the brand names Combiva II For Cats & CrossBlock II For Cats
- EPA Reg. No. 83399-17 sold under the brand names Combiva II For Dogs and Puppies & CrossBlock II For Dogs and Puppies

We trust this information satisfies EPA FIFRA Section 6(a)(2) reporting requirements. Please contact me by phone at 913-754-7668 or by e-mail at [alicia.henk@ceva.com](mailto:alicia.henk@ceva.com) if any additional information is required.

Sincerely,

A handwritten signature in black ink that reads "Alicia Henk". The signature is written in a cursive, flowing style.

Alicia Henk  
Director,  
Development and Pharmaceutical Regulatory Affairs



CC: California Department of Pesticide Registrations  
Adverse Effects Reporting  
1001 I Street  
P.O. Box 4015  
Sacramento, CA 95812-4015

New York Department of Environmental Conservation  
Office of Pesticides  
625 Broadway  
Albany, NY 12233-4500

FIFRA 6(a)(2) Adverse Effects Reporting Aggregate Report Form

**FIFRA 6 (a)(2) Aggregate Adverse Effect Information Submission Form**

Period Covered: 3rd Quarter (Jul-Sep) 2016

Submission Date: 30 Nov 16

EPA Reg. No.: 83399-12

Page: 1 of 1

Product Name: Vectra Pro Flea Spray

-001

Active Ingredients: Dinotefuran

	<b>Exposure Types and Severity Category Designations</b>						
<b>Total Incidents</b>	<b>H-D</b>	<b>H-E</b>	<b>D-A<sup>A</sup></b>	<b>D-B</b>	<b>D-C</b>	<b>D-D</b>	<b>D-E</b>
1	0	0	1	0	0	0	0

**<sup>A</sup> Case Details:**

**2015-US-003097:**

On 13 Aug 16, Saint (4.5mo, 5lb, male, intact, Siamese, cat) in unknown health condition, being treated for an upper respiratory infection, with a history of fleas, had Vectra Pro Flea Spray (lot unknown) topically by the owner for the treatment of fleas. The owner applied one spray between the ears and two sprays on the belly and rubbed the product into the skin. This was the first time this product was applied. Clavamox was administered concomitantly.

On 13 Aug 16, ten minutes post application the cat exhibited dilated pupils, increased respirations, and aggressive behavior. The cat was not examined by the veterinarian and no treatment was administered.

On 14 Aug 16, five hours post application the cat started coughing up blood. The cat was not examined by the veterinarian and no treatment was administered. Ten hours post application the cat exhibited agonal breathing and natural death. The owner declined necropsy.

On 14 Aug 16, the patient died. The reported events are not typical or known to occur with the use of the product and with concomitant products administered it is impossible to determine what role, if any, the product played in the event. This case is closed.

## FIFRA 6(a)(2) Adverse Effects Reporting Aggregate Report Form

### FIFRA 6 (a)(2) Aggregate Adverse Effect Information Submission Form

Period Covered: 3rd Quarter (Jul-Sep) 2016

Submission Date: 30 Nov 16

EPA Reg. No.: 83399-16

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Product Name: Combiva II For Cats

Active Ingredients: Imidacloprid, Pyriproxyfen

	Exposure Types and Severity Category Designations						
Total Incidents	H-D	H-E	D-A	D-B	D-C	D-D	D-E
0	0	0	0	0	0	0	0

## FIFRA 6(a)(2) Adverse Effects Reporting Aggregate Report Form

### FIFRA 6 (a)(2) Aggregate Adverse Effect Information Submission Form

Period Covered: 3rd Quarter (Jul-Sep) 2016

Submission Date: 30 Nov 16

EPA Reg. No.: 83399-16

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Product Name: CrossBlock II For Cats

Active Ingredients: Imidacloprid, Pyriproxyfen

	Exposure Types and Severity Category Designations						
Total Incidents	H-D	H-E	D-A	D-B	D-C	D-D	D-E
0	0	0	0	0	0	0	0

## FIFRA 6(a)(2) Adverse Effects Reporting Aggregate Report Form

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Period Covered: 3rd Quarter (Jul-Sep) 2016

Submission Date: 30 Nov 16

EPA Reg. No.: 83399-17

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Product Name: Combiva II For Dogs & Puppies

Active Ingredients: Imidacloprid, Pyriproxyfen

	Exposure Types and Severity Category Designations						
Total Incidents	H-D	H-E	D-A	D-B	D-C	D-D	D-E
0	0	0	0	0	0	0	0

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Period Covered: 3rd Quarter (Jul-Sep) 2016

Submission Date: 30 Nov 16

EPA Reg. No.: 83399-17

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Product Name: CrossBlock II For Dogs & Puppies

Active Ingredients: Imidacloprid, Pyriproxyfen

	Exposure Types and Severity Category Designations						
Total Incidents	H-D	H-E	D-A	D-B	D-C	D-D	D-E
0	0	0	0	0	0	0	0

# FIFRA 6(a)(2) Adverse Effects Reporting Aggregate Report Form

## FIFRA 6 (a)(2) Aggregate Adverse Effect Information Submission Form

Period Covered: 3rd Quarter (Jul-Sep) 2016

Submission Date: 30 Nov 16

EPA Reg. No.: 83399-6

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Product Name: Vectra 3D For Dogs

Active Ingredients: Dinotefuran, Pyriproxyfen, Permethrin

-002

Total Incidents	Exposure Types and Severity Category Designations						
	H-D	H-E	D-A <sup>A</sup>	D-B	D-C	D-D	D-E
271	19	1	1	9	35	206	0

### <sup>A</sup> Case Details:

#### **2015-US-003154:**

On an unspecified date Apr 2016, Yay (canine, 9.5yr, 71.4lb, neutered, male, Staffordshire Bull Terrier) in good condition, with no previous medical history, received Vectra 3D 56-95lb (Lot unknown, 6pk) one tube, topically, by the owner, for the prevention of fleas and ticks. This was the first application. No other products were administered concurrently. On 07 Jun 16, a Complete Blood Count and Chemistry Panel were performed and the PCV was 14%. Immune-Mediated Hemolytic Anemia (IMHA) was diagnosed. On 16 Jul 16, an unknown time post application the dog was euthanized due to progression of the IMHA. Significant systemic side effects are not normally seen with the use of this topical product. This case is closed.



# FIFRA 6(a)(2) Adverse Effects Reporting Aggregate Report Form

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Period Covered: 3rd Quarter (Jul-Sep) 2016

Submission Date: 30 Nov 16

EPA Reg. No.: 83399-6

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-003

Product Name: SimpleGuard 3 For Dogs

Active Ingredients: Dinotefuran, Pyriproxyfen, Permethrin

	Exposure Types and Severity Category Designations						
Total Incidents	H-D	H-E	D-A	D-B	D-C	D-D	D-E
29	3	0	0	3	5	18	0

# FIFRA 6(a)(2) Adverse Effects Reporting Aggregate Report Form

## FIFRA 6 (a)(2) Aggregate Adverse Effect Information Submission Form

Period Covered: 3rd Quarter (Jul-Sep) 2016

Submission Date: 30 Nov 16

EPA Reg. No.: 83399-6-85581

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-004

Product Name: First Shield Trio For Dogs

Active Ingredients: Dinotefuran, Pyriproxyfen, Permethrin

Total Incidents	Exposure Types and Severity Category Designations					
	H-D	H-E	D-A <sup>A</sup>	D-B	D-C	D-D
47	5	0	1	0	9	32

### <sup>A</sup> Case Details: 2016-US-003464

On 03 Aug 16, Keller (15yr, 10 mo, 27.2lb, MN, Shih Tzu) in fair health, with a history of geriatric issues, cataracts OU, and patellar luxation, had First Shield Trio 21-55lb (lot unknown, single dose) applied topically, by the owner, for the prevention of fleas and ticks. This was the first time this product was applied. There were no concomitant products administered. On 15 Aug 16, twelve days post application the owner elected to euthanize the dog. There was no necropsy performed. Pruritus is a known labeled possible side effect of the product. Significant systemic effects are not common. This case is closed.

# FIFRA 6(a)(2) Adverse Effects Reporting Aggregate Report Form

## FIFRA 6 (a)(2) Aggregate Adverse Effect Information Submission Form

Period Covered: 3rd Quarter (Jul-Sep) 2016

Submission Date: 30 Nov 16

-005

EPA Reg. No.: 83399-9

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Product Name: Vectra for Cats/ Vectra for Cats and Kittens

Active Ingredients: Dinotefuran, Pyriproxyfen

	Exposure Types and Severity Category Designations						
Total Incidents	H-D	H-E	D-A	D-B	D-C	D-D	D-E
40	3	0	0	2	3	32	0

# FIFRA 6(a)(2) Adverse Effects Reporting Aggregate Report Form

## FIFRA 6 (a)(2) Aggregate Adverse Effect Information Submission Form

-006

Period Covered: 3rd Quarter (Jul-Sep) 2016

Submission Date: 30 Nov 16

EPA Reg. No.: 83399-9

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Product Name: SimpleGuard for Cats

Active Ingredients: Dinotefuran, Pyriproxyfen

	Exposure Types and Severity Category Designations						
Total Incidents	H-D	H-E	D-A	D-B	D-C	D-D	D-E
4	0	0	0	1	1	2	0

# FIFRA 6(a)(2) Adverse Effects Reporting Aggregate Report Form

## FIFRA 6 (a)(2) Aggregate Adverse Effect Information Submission Form

Period Covered: 3rd Quarter (Jul-Sep) 2016

Submission Date: 30 Nov 16

EPA Reg. No.: 83399-9-85581

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Product Name: FirstShield for Cats/ FirstShield for Cats and Kittens

Active Ingredients: Dinotefuran, Pyriproxyfen

-007

	Exposure Types and Severity Category Designations						
Total Incidents	H-D	H-E	D-A	D-B	D-C	D-D	D-E
1	0	0	0	0	0	1	0

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### FIFRA 6 (a)(2) Aggregate Adverse Effect Information Submission Form

Period Covered: 3rd Quarter (Jul-Sep) 2016

Submission Date: 30 Nov 16

EPA Reg. No.: 83399-10

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Product Name: Vectra for Dogs and Puppies

Active Ingredients: Dinotefuran, Pyriproxyfen

-008

	Exposure Types and Severity Category Designations						
Total Incidents	H-D	H-E	D-A	D-B	D-C	D-D	D-E
5	0	0	0	0	1	4	0

## FIFRA 6(a)(2) Adverse Effects Reporting Aggregate Report Form

### FIFRA 6 (a)(2) Aggregate Adverse Effect Information Submission Form

Period Covered: 3rd Quarter (Jul-Sep) 2016

Submission Date: 30 Nov 16

EPA Reg. No.: 83399-10-85581

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Product Name: First Shield for Dogs and Puppies

Active Ingredients: Dinotefuran, Pyriproxyfen

-009

	Exposure Types and Severity Category Designations						
Total Incidents	H-D	H-E	D-A	D-B	D-C	D-D	D-E
5	1	0	0	0	0	4	0